

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	H	ATTORNEY'S DOCKET NO.
08/187,879	01/27/94	ROBINSON		

HM31/0526

CLARK, EXAMINER

PATRICIA GRANAHAN  
HAMILTON, BROOK, SMITH & REYNOLDS  
TWO MILITIA DRIVE  
LEXINGTON MA 02173

ART. UNIT	PAPER NUMBER
-----------	--------------

#29  
05/26/98

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.  
08/187,879

Applicant(s)

Robinson et al.

Examiner

Deborah Clark

Group Art Unit

1633

 Responsive to communication(s) filed on Mar 9, 1998 This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

 Claim(s) 44-51, 62-64, 67-72, 74, and 78-89 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

 Claim(s) \_\_\_\_\_ is/are allowed. Claim(s) 44-51, 62-64, 67-72, 74, and 78-89 is/are rejected. Claim(s) \_\_\_\_\_ is/are objected to. Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

 See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner. The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

 Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

 Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_ Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1633

### **DETAILED ACTION**

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633, the examiner is now Deborah Clark.

#### *Response to Amendment*

2. Applicant's amendment and response to the prior office action has been received, 03/09/98, and entered, paper no. 28. Claims 44-51, 62-64, 67-72, 74, and 78-89 are now pending.
3. Applicant's correction of table 6 is acknowledged.

#### *Double Patenting*

4. The rejection made under 35 USC 101 is moot, as the rejected claims have been canceled.
5. The rejection made under the judicially created doctrine of obvious-type double patenting is withdrawn due to applicant's comments.

#### *Claim Rejections - 35 USC § 112*

6. The rejection under 35 USC 112, 2nd paragraph is withdrawn as the rejected claims have been canceled.

Art Unit: 1633

7. The rejection made over the scope of claims 1-3, 5, 6, 11-25, 30-37, 42, 43, 52-58, 61, and 75 is moot as the claims have been canceled. Applicant's attorney traverses the assessment made over the declaration of Dr. Robinson (see paper no. 28, page 8). It is acknowledged that some of the macaques in the study had reduced viral loads and went longer without signs of AIDS. However, it should also be noted that the constructs used in that experiment were not the same as those disclosed herein and could not have been derived from the teachings in the specification at the time the invention was made. Nevertheless, the claims have been canceled.

8. Claims 44-51, 62-64, 69-74 stand, and claims 78-89 are rejected under 35 USC 112, 1st paragraph. Applicants refer to the argument addressed above that a demonstration of protection in macaques was disclosed (see paper no. 28, page 8). However, as pointed out above, the specification does not provide guidance or direction which would have lead one to make the constructs used in the experiments submitted by declaration. In regards to the Weiss reference, this reference is relevant because the reference does not report something that is new at the time of publication. Hence, the facts presented in the article were that same at the time the invention was made.

Experimentation conducted *in vitro* or in models not accepted by the art (such as the mice applicants point to (see paper no. 28, page 9)) cannot be extrapolated to the human *in vivo* environment.

Art Unit: 1633

Claims 78-80 were not previously included in this rejection. This is felt to be an oversight. The specification does not suggest or imply any use for the vectors other than vaccines. Therefore, these claims have not been enabled for use.

Applicants may file another declaration under rule 1.132 using the constructs taught by the specification and reduce the scope of the claims to only encompass those constructs. At such time, this rejection would be overcome.

***Claim Rejections - 35 USC § 102***

9. The previously made rejections under 35 USC 102 are withdrawn due to applicant's amendment.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. Claims 44, 51, 81, 83, and 89 are rejected under 35 U.S.C. 102(e) as being anticipated by Wolff et al., US 5,693,622.

Wolff et al. discloses SCID mice which were injected intravenously through the tail vein with a nucleic acid vaccine which encoded the nef gene. The mice showed a 2 fold reduction in the number of cells infected and are reported as a moderate anti-viral effect (see column 28,

Art Unit: 1633

example 9). The plasmid contained a promoter which was not of retroviral origin (see column 7, lines 41-63). Therefore, the claims are anticipated.

12. Claim rejected under 35 U.S.C. 102(e) as being anticipated by Felgner et al., US 5,703,055.

Felgner et al. discloses SCID mice which were injected intravenously through the tail vein with a nucleic acid vaccine which encoded the nef gene. The mice showed a 2 fold reduction in the number of cells infected and are reported as a moderate anti-viral effect (see column 31, example 9). The plasmid contained a promoter which was not of retroviral origin (see column 10, lines 50-53 and column 11, lines 1-15). Therefore, the claims are anticipated.

### ***Conclusion***

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Clark whose telephone number is (703) 305-4051. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196. Papers related to this application may be submitted to art unit 1633 by facsimile transmission. Papers should be faxed to art unit 1633 via the PTO Fax Center located in Crystal Mall 1. The Fax Center Number is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

*Jasemine C. Chambers*  
JASEMINE C. CHAMBERS, PH.D.  
SUPERVISORY PATENT EXAMINER  
GROUP 1800/600

Serial Number: 08/187,879

Page 6

Art Unit: 1633

DRC

05/18/98